EPA Reg. Jacket 91460-8

PROCESSING REQUEST

Reg # 91640-8 D	ecision # 520227
Description: New Basic + Altern	ale 1 CSFs
Electronic Label & Letter	Non Electronic
(see PPLS):	Label & Letter
(300 11 120).	(Scanning required):
☐ Dated:	□ Dated:
Only one label type al	sould be releated
***Only one label type sh	ionid de selected
	•
Other Materials Sent (see jack	ket):
New CSF(s) Dated: 7/31/2016	
U Other:	
File this coversheet and attached materials in and clipped together, NOT STAPLED. Then gi materials to staff in the Information Services jacket is full or only available as an image, plobring it down to the (ISC). For further inform	ve the jacket with the coversheet and Center (ISC) (Room S-4900). If a ease file materials in a new jacket and
Reviewer: Tim Ciaclo	
Reviewer: Tim Ciaclo Division: RD/IUB1	
Phone: 703-347-8082	Date: 7/20/2017



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460

91640-8

Date of Issuance:

EPA Reg. Number:

7/20/17

NOT:	CE.	OF	PES1	$\Gamma[C]$	DE:

X Registration Reregistration (under FIFRA, as amended)

Term of Issuance: Conditional

Name of Pesticide Product: Bifenthrin Technical

Name and Address of Registrant (include ZIP Code):

Glenda Haage Agent GenMerica NA, LLC 1660 3rd Ave SW Lemars, IA 51031

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official: Date: 7/20/17 Elizabeth Fertich Acting Product Manager 03, Invertebrate & Vertebrate Branch 1 Registration Division (7505P)

Page 2 of 3 EPA Reg. No. 91640-8 Decision No. 520227

EPA Form 8570-6

2. You are required to comply with the data requirements described in the DCIs and EDSP Orders identified below:

a. Bifenthrin GDCI-128825-902 GDCI-128825-1114 GDCI-128825-1158 GDCI-128825-1159 EDSP-128825-66 EDSP-128825-67 EDSP-128825-68 EDSP-128825-70 EDSP-128825-71 EDSP-128825-73 EDSP-128825-962

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCIs or EDSP Orders listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://www.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-pesticide-re-evaluation-division

- 3. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 91640-8."
- 4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 07/31/2016
- Alternate CSF 1 dated 07/31/2016

Page 3 of 3 EPA Reg. No. 91640-8 Decision No. 520227

If you have any questions, please contact Tim Ciarlo by phone at 703-347-8082, or via email at <u>Ciarlo.Timothy@epa.gov</u>.

BIFENTHRIN TECHNICAL

Active ingredient:	
Bifenthrin:2-methyl[1,1'-biphenyl]-3-yl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)	
-2,2-dimethyl-cyclopropanecarboxylate*	98.7%
OTHER INGREDIENTS:	1.3%
Total	100.0%

A -41: -- 1-- -- -- -1: - -- 4:

ACCEPTED

07/20/2017

Under the Federal Insecticide, Fungicide and Rodenlicide Act as amended for the pesticide registered under EPA Reg. No. 91640-8

WARNING

KEEP OUT OF REACH OF CHILDREN

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID					
IF SWALLOWED:	 Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person. 				
IF INHALED:	 Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice 				
IF ON SKIN OR CLOTHING:	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. 				
IF IN EYES:	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. 				
	ainer or label with you when calling a poison control center or physician, or going for so contact 1-800-222-1222 for emergency medical treatment information				

EPA Reg. No. 91	640-xx	
EPA Est. No		
NET WEIGHT: _	LBS (KG)

Manufactured For GenMerica NA, LLC 109 E. 17TH ST., Cheyenne, WY 82001

^{*}Cis isomers 97% minimum, trans isomers 3% maximum.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS WARNING

May be fatal if swallowed. Harmful if inhaled or absorbed through skin. Causes moderate eye irritation. Avoid breathing vapor or spray mist. Avoid contact with skin, eyes or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco or using the toilet.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

PHYSICAL/CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. FOR FORMULATING USE ONLY.

Formulators using this product are responsible for obtaining EPA registration of their formulated products.

Legume Vegetables (Succulent

Shelled and Dried Shelled)

(1) Only for formulation into an insecticide/miticide for the following sites of use:

Artichokes (Globe) Cotton Bananas (import only) Crambe Beet, Garden (roots and tops) Cucurbit Vegetables Group Brassica, head and stem Fruiting Vegetables Crop Group (subgroup 5A, except Cabbage) Grapes Brassica, leafy greens Head and Stem Brassica (subgroup 5B) Vegetables Bushberries Herbs (subgroup 19A) Cabbage Hops Caneberry Leafy Petioles Vegetables Canola Legume Vegetables

Coriander Lettuce (head)
Corn (Field, Sweet, Popcorn) Mayhaw
(Field, Sweet, Popcorn Grown
for Seed) (Grain and Silage) Peanut

Pear Radish (tops) Rapeseed

Root and Tuber Vegetables Group (subgroup 1B) (except Sugar Beet and Garden Beet)

Soybean Spinach Strawberry Tobacco

Tree Nut Group (Crop Group 14),

Including Pistachios

Tuberous and Corm Vegetables

(subgroup 1C) Turnip Greens

Terrestrial Non-Food:

- Termiticide and Soil Contact Non-fumigation Treatment
- Wood Treatment and Protection
- Christmas trees

Citrus Crop Group

Cilantro

- Conifer Seed Orchards
- Nonbearing Fruit and Nut Trees
- Greenhouse Grown Ornamental Trees, Shrubs, Plants, Flowers
- Outdoor Insect Control

- Indoor Insect Control
- Residential Lawns
- Ornamental Plants, Trees, Shrubs, and Vines (Woody)
- Turfgrass (including golf courses), Sod Farms
- Grass Forage Fodder and Hay Group
- · Grass Grown for Seed and Pasture and Rangeland

Food Handling Establishments:

- Places other than private residences in which food is held, processed, prepared, or served.
- (2) Uses for which U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
- (3) Uses for experimental purposes that are in compliance with U.S. EPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Keep out of reach of children and animals. Store in original containers only. Store in a cool, dry place and avoid excess heat. Carefully open containers. After partial use, replace lids and close tightly. Do not contaminate other pesticides, fertilizers, water, food, or feed by storage or disposal.

To confine spill: If liquid, dike surrounding area or absorb with sand, cat litter, or commercial clay. If dry material, cover to prevent dispersal. Place damaged package in a holding container. Identify contents.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. Dispose of excess waste or pesticide by use according to label directions, or contact your State Pesticide or Environmental Control Agency, or Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Completely empty container into formulating equipment by shaking and tapping sides and bottom to loosen clinging particles. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. Offer for recycling, if available, or reconditioning if appropriate. If recycling is not available, puncture and dispose of in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke. If rinsate cannot be used, follow pesticide disposal instructions.

WARRANTY DISCLAIMER

The directions for use of this product must be followed carefully. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, (1) THE GOODS DELIVERED TO YOU ARE FURNISHED "AS IS" BY MANUFACTURER OR SELLER, AND (2) MANUFACTURER AND SELLER MAKE NO WARRANTIES, GUARANTEES, OR REPRESENTATIONS OF ANY KIND TO BUYER OR USER, EITHER EXPRESS OR IMPLIED, OR BY USAGE OF TRADE, STATUTORY OR OTHERWISE. WITH REGARD TO THE PRODUCT SOLD, INCLUDING, BUT NOT MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, USE, OR ELIGIBILITY OF THE PRODUCT FOR ANY PARTICULAR TRADE USAGE. UNINTENDED CONSEQUENCES, INCLUDING BUT NOT LIMITED TO INEFFECTIVENESS, CROP OR PLANT DAMAGE, OR LOSS OF YIELD, MAY RESULT BECAUSE OF SUCH FACTORS AS THE PRESENCE OR ABSENCE OF OTHER MATERIALS USED IN COMBINATION WITH THE GOODS, OR THE WEATHER, WIND, AND TEMPERATURE, OR THE MANNER OF USE OR APPLICATION, ALL OF WHICH ARE BEYOND THE CONTROL OF MANUFACTURER OR SELLER, AND ASSUMED BY BUYER OR USER. THIS WRITING CONTAINS ALL OF THE REPRESENTATIONS AND AGREEMENTS BETWEEN BUYER OR MANUFACTURER, AND SELLER, AND NO PERSON OR AGENT OF MANUFACTURER OR SELLER HAS ANY AUTHORITY TO MAKE ANY OTHER REPRESENTATION OR WARRANTY OR AGREEMENT RELATING IN ANY WAY TO THESE GOODS. NO WARRANTIES SHALL BE CREATED BY COURSE OF DEALING, USAGE OF TRADE, OR COURSE OF PERFORMANCE. THERE ARE NO WARRANTIES THAT EXTEND BEYOND THE FACE

HEREOF. THE SELLER AND MANUFACTURER ASSUME NO RESPONSIBILITY THAT THE GOODS WILL BE FIT FOR ANY PARTICULAR PURPOSE FOR WHICH YOU MAY BE BUYING OR USING THE GOODS.

LIMITATION OF LIABILITY WARNING

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL MANUFACTURER OR SELLER BE LIABLE FOR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, OR FOR DAMAGES IN THEIR NATURE OF PENALTIES RELATING TO THE GOODS SOLD, INCLUDING USE, APPLICATION, HANDLING, AND DISPOSAL. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NEITHER MANUFACTURER NOR SELLER SHALL BE LIABLE TO BUYER OR USER OR TO CUSTOMERS OF BUYER, IF ANY, FOR INDEMNIFICATION OR ANY DAMAGES OR SUMS OF MONEY, CLAIMS OR DEMANDS WHATSOEVER, RESULTING FROM OR BY REASON OF, OR RISING OUT OF THE USE, MISUSE, OR FAILURE TO FOLLOW LABEL WARNINGS OR INSTRUCTIONS FOR USE, OF THE GOODS SOLD. ALL SUCH RISKS SHALL BE ASSUMED BY THE BUYER, USER, OR CUSTOMERS. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BUYER'S OR USER'S EXCLUSIVE REMEDY, AND MANUFACTURER'S OR SELLER'S TOTAL LIABILITY, SHALL BE FOR DAMAGES NOT EXCEEDING THE PURCHASE PRICE OF THE GOODS AND, IF BUYER OR USER WISHES, THE RETURN OF THE GOODS BY BUYER TO SELLER.

If you do not agree with or do not accept any of directions for use, the warranty disclaimers, or limitations on liability, do not use the goods, and return it unopened to the Seller, and the purchase price will be refunded. By using the goods, you expressly agree to all of the terms and conditions of this contract.

Prop20170719

Please read instructions on reverse l	before completing fo				Form	proved, OMI	B No. 2070-0	0060, Approval expires 2-28-95
≎ EPA		United State mental Protec Washington, DC	ction Agency		X	Registrat Amendm Other		OPP Identifier Number
		Application	on for Pestic	ide - Sect	ion I			
1. Company/Product Number	91640-		2. EPA	A Product Man Da			3. Propos	sed Classification
4. Company/Product (Name) Bifenthrin Techn	nical		PM#	23	3		⋉ None	e Restricted
5. Name and Address of Applica	ant (Include Zip Code)	1		edited Review. milar or identi				ection 3(c)(3)(b)(i), my product g to:
GenMerica NA, LLC 1660 3 rd Ave SW LeMars, Iowa 51031			EP	A Reg. No.	279-30	055		
☐ Chec	eck if this is a new addre	ess	7					
Amandmant Evalain hal			Section – I	1	7-7-2-		* 1.44	
Amendment - Explain bel		d	<u> </u>	Final printed la Me Too" Appl		response to F	Agency lette	er dated
Notification - Explain belo	эw		_ c	Other - Explain	ı below			
Explanation: Use additional pag	ge(s) if necessary. (For	Section I and Se						
PRIA Action Code R334-1	1 month review- \$1	.9838.00 fee						
			Section - I	II				
1. Material This Product Will E								
Child-Resistant Packaging	Unit Packaging		Water Soluble	Packaging	2	2. Type of Co		
☐ Yes*	Yes		☐ Yes			تت	Metal Plastic	
* Certification must be submitted	If "Yes" Unit Packaging wt.	No. per container	If "Yes" Package wt.	No. per container		☐ G	Flastic Glass Paper Other (Spec	cify)
3. Location of Net Contents Info	ormation	4. Size(s) Retai	il Container		5. Loca	ation of Label	l Direction:	s
⋉ Label □	Container		40, 50 LBS	. !	On On	Label Labeling acc	companyin	g product
6. Manner in Which Label is Af	ffixed to Product	Lithograp Raper glue	•		□ Ste	enciled her		
<u> </u>			Section - Γ	<u></u>				
1. Contact Point (Complete items	s directly below for ider	ntification of indi	vidual to be contac	cted, if necessa	ry, to pr	rocess this ap	plication.)	
Name Glenda Haage		Ti	itle	Agent			•	No. (Include Area Code) 712-540-6290
I certify that the staten I acknowledge that any kno applicable law.			attachments there			_	te.	8. Data Application Received (Stamped)
2. Signature		3.	Title					
James Harry				Ageı	nt 			
4. Typed Name Glenda Haage		5.	Date	2016-0	7-31			

July 31, 2016

Document Processing Desk Office of Pesticide Programs (7504P) US EPA One Potomac Yard 2777 Crystal Drive, Room S-4900 Arlington, VA 22202

Subject: Application to register Bifenthrin Technical (EPA Reg. No. 91640-xx)

Dear Sir or Madam;

The starting materials (830.1600) and the production process (830.1620) for are the same. This is supported by the fact the impurities present in the formula are substantially similar.

If you have any questions or concerns regarding this information, please contact me at 712-540-6290 or glenda@consultghb.com.

Sincerely,

Glenda Haage Regulatory Consultant

Lieun Frank

Transmittal Document

Name and Address of Submitter:

GenMerica NA, LLC 1660 3rd Ave SW LeMars, Iowa 51031

Company No. 91640

Contact Person:

Glenda Haage

712-540-6290

glenda@consultghb.com

Regulatory Actions:

Submission of supportive documents for registration

Transmittal Date:

July 31, 2016

Listed of Submitted Studies:

	Volume No.	Guideline Requirement	Study Title	
9989101	1	830.1150, 830.1600, 830.1620, 830.1670, 830.1750, 830.1800,	Product Identity and Composition, Description of the Materials used, Description of the Production Process, Discussion of the Formation of Impurities, Certified Limits, and Enforcement of Analytical method for Bifenthrin Technical	
9989102	2	830.1700, 830.1800	Preliminary Analysis of Bifenthrin Technical	-
9989103	3	830.1700, 830.1800	Preliminary Analysis and Enforcement of Analytical method of Bifenthrin TGAI-Validation of Analytical Methodology for the Assay of Active Ingredient and Related Significant Impurities and Subsequent 5-Batch Analysis of Bifenthrin TGAI	
9989104	4	830.1700, 830.1800	Determination of 3D spectra, Identification of Active Ingredient and Impurities for 5 Batches of Bifenthrin TGAI as amendment to. * * * * * study NC-2008-022	
9989105	5	830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.7000, 830.7050, 830.7200, 830.7300, 830.7370, 830.7550, 830.7840,	Product Chemistry of Bifenthrin Technical	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$
'			6 6 8 2465 2 1 1 2 2 3 4 4 4 4 5 4 4 5 4 5 4 5 4 5 4 5 7 6 7 7 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$
			\$ 3 \$ \$ # E \$	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

WASHI	NGTON, D.C. 2046	,
Paperwork Reduction Act Notice: The public reporting burden for this registration and 0.25 hours per response for reregistration and special in necessary forms. Send comments regarding burden estimate or any other burden to: Director, OPPE Information Management Division (2137), UDo not send the completed form to this address.	eview activities, including ner aspect of this collectio	time for reading the instructions and completing the not information, including suggestions for reducing the
Certification with	n Respect to Citation	on of Data
Applicant's/Registrant's Name, Address, and Telephone N GenMerica NA, LLC,1660 3rd Ave SW, LeMars, Iowa 51031; 7	umber 712-540-6290	EPA Registration Number/File Symbol 91640-xx
Active Ingredient(s) and/or Representative Test Compoun bifenthrin	d(s)	Date 2017-07-12
General Use Pattern(s) (list all those claimed for this product terrestrial food, terrestrial feed	using 40 CFR Part 158	
NOTE: If your product is a 100% repackaging of another purch you do not need to submit this form. You must submit the form		
I am responding to a Data-Call-In Notice, and have included Matrix form should be used for this purpose).	led with this form a list	of companies sent offers of compensation (the Data
SECTION I: METHOD OF D	ATA SUPPORT (ch	eck one method only)
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Dat Matrix form should be used for this purpose	I am using the se selective method), ar	lective method of support (or cite-all option under the id have included with this form a completed list of data ta Matrix form must be used)
SECTION II: (GENERAL OFFER	O PAY
(Required if using the cite-all method or when using the cite-al requirements.) I hereby offer and agree to pay compensation, to other per EIDDA	·	
by FIFRA.	LIN OFFICIOATIO	
I certify that this application for registration, this form for re	IIII: CERTIFICATIO	
or cited in the application for registration, the form for reregistration under the selective method is indicated in Section I, this properties or effects of this product or an identical or substanti is a type of data that would be required to be submitted under the application sought the initial registration of a product of ide	ation, or the Data-Call- application is support ally similar product, or the data requirements	In response. In addition, if the cite-all option or cite-all ed by all data in the Agency's files that (1) concern the one or more of the ingredients in this product; and (2) in effect on the date of approval of this application if
I certify that for each exclusive use study cited in support that I have obtained the written permission of the original data	of this registration or re submitter to cite that s	eregistration, that I am the original data submitter or tudy.
I certify that for each study cited in support of this registrated original data submitter; (b) I have obtained the permission of the periods of eligibility for compensation have expired for the study company that submitted the study and have offered (I) to pay of FIFRA; and (II) to commence negotiations to determine the study.	ne original data submith ly; (d) the study is in the compensation to the ex	er to use the study in support of this application; (c) all e public literature; or (e) I have notified in writing the tent required by sections 3(c)(1)(F) and/or 3(c)(2)(B)
I certify that in all instances where an offer of compensati delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(E) Should I fail to produce such evidence to the Agency upon required suspend the registration of my product in conformity with FIFR	of FIFRA are available uest, I understand that A.	le and will be submitted to the Agency upon request. the Agency may initiate action to deny, cancel or
I certify that the statements I have made on this form and any knowingly false or misleading statement may be punishab	all attachments to it and le by fine or imprisonment	e true, accurate, and complete. I acknowledge that ent or both under applicable law.
Signature	Date	Typed or Printed Name and Title
Similar Arrange	2017-07-12	Glenda Haage, Regulatory Agent

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.



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		DATA MATRIX			
Date 2017-07-12		EPA Reg. No./File Symbol 91640-xx	Page 1 of 11		
Applicant's/Registrant's Name & Address GenMerica NA LLC % GHB Consulting, 1660 3 rd Ave SW, LeMars, IA 51031		Product Bifenthrin Technical			
Ingredient bifenthrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry Group A	Product Identity, Composition, and Analysis Test Guidelines	49989101; 49989102; 49989103; 49989104	GenMerica NA LLC	OWN	
Product Chemistry Group B	Physical/Chemical Properties Test Guidelines	49989105	GenMerica NA LLC	OWN	
OPPTS 870.1100	Acute Oral Toxicity	Cite All	See registrants listed on pages 2 -11	Pay	
OPPTS 870.1200	Acute Dermal Toxicity	Cite All	See registrants listed on pages 2 -11	Pay	
OPPTS 870.1300	Acute Inhalation Toxicity	Cite All	See registrants listed on pages 2 -11	Pay	
OPPTS 870.2400	Acute Eye Irritation	Cite All	See registrants listed on pages 2 -11	Pay	
OPPTS 870.2500	Acute Dermal Irritation	Cite All	See registrants listed on pages 2 -11	Pay	
OPPTS 870.2600	Skin Sensitization	Cite All	See registrants listed on pages 2 -11	Pay	
Signature			Name and Title		Date
Berein Honge			Glenda Haage, Regulatory Agent		2017-07-12
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		DATA MATRIX			
Date 2017-07-12			EPA Reg. No./File Symbol 91640-xx	Page 2 of 11	
Applicant's/Registrant's Name & Address GenMerica NA LLC % GHB Consulting, 1660 3 rd Ave SW, LeMars, IA 51031		Product Bifenthrin Technical			
ngredient bifenthrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Generic Data Requirements	Cite all utilized for generic data requirements.	Cite All	Syngenta Crop Protection, LLC PO Box 18300, 410 Swing Road Greensboro, NC 27419	Pay	
		Cite All	NuFarm Americas, Inc. 4020 Aerial Center Pkwy, Ste 101 Morrisville, NC 27560	Pay	
		Cite All	The Scotts Company d/b/a The Ortho Group 14111 Scottslawn Road Marysville, OH 43041	Pay	
		Cite All	Bayer CropScience LP PO Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Pay	
		Cite All	FMC Corporation 2929 Walnut Street Philadelphia, PA 19104	Pay	
		Cite All	Bayer Environmental Science A Division of Bayer CropScience LP 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Pay	
		Cite All	BASF Corporation PO Box 13528, 26 Davis Drive Research Triangle Park, NC 27709	Pay	
Signature Brough			Name and Title Glenda Haage, Regulatory Agent		Date 2017-07-12
EDA E 0570 05 (0.07) El	Stronic and Daner versions available. Submit only Paner		Agoney Internal		

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



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		DATA MATRIX			
Date 2017-07-12			EPA Reg. No./File Symbol 91640-xx	Page 3 of 11	
Applicant's/Registrant's Name & Address GenMerica NA LLC % GHB Consulting, 1660 3 rd Ave SW, LeMars, IA 51031			Product Bifenthrin Technical		
Ingredient bifenthrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite All	The Scotts Company 14111 Scottslawn Road Marysville, OH 43041	Pay	
		Cite All	Lebanon Seaboard Corporation 1600 E Cumberland Street Lebanon, PA 17042	Pay	
		Cite All	McLaughlin Gormley King Company d/b/a MGK 8810 Tenth Ave N Minneapolis, MN 55427	Pay	
		Cite All	Fuller System, Inc. PO Box 3053 Woburn, MA 01888	Pay	
		Cite All	Sergeant's Pet Care Products, Inc. PO Box 540399 Omaha, NE 68154	Pay	
		Cite All	ACETO Agricultural Chemicals Corp. 4 Tri Harbor Court Port Washington, NY 11050	Pay	
		Cite All	S.C. Johnson & Son Inc. 1525 Howe Street Racine, WI 53403	Pay	
Signature			Name and Title Glenda Haage, Regulatory Agent		Date 2017-07-12

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		DATA MATRIX			
Date 2017-07-12			EPA Reg. No./File Symbol 91640-x	Page 4 of 11	
Applicant's/Registrant's Name & Address GenMerica NA LLC % GHB Consulting, 1660 3 rd Ave SW, LeMars, IA 51031		Product Bifenthrin Technical			
ngredient bifenthrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite All	AMVAC Chemical Corporation 4695 McArthur Court, Suite 1200 Newport Beach, CA 92660	Pay	
		Cite All	Helena Chemical Company Helena Products Group 7664 Smythe Farm Road Memphis, TN 38120	Pay	
		Cite All	Southern States Cooperative, Inc. Registrations by Design, Inc. PO Box 1019 Salem, VA 24153	Pay	
		Cite All	Nippon Soda Co., Ltd. NISSO America Inc. 88 Pine Street, 14 th Floor New York, NY 10005	Pay	
		Cite All	The Andersons, Inc. PO Box 119, 1947 Briarfield Blvd Maumee, OH 43537	Pay	
		Cite All	Sunniland Corporation PO Box 8001 Sanford, FL 32772	Pay	
Signature Signature		<u> </u>	Name and Title Glenda Haage, Regulatory Agent		Date 2017-07-12

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		DATA MATRIX			
		DATA WATRIA			
Pate 2017-07-12	ate 2017-07-12		EPA Reg. No./File Symbol 91640-xx	Page 5 of 11	
Applicant's/Registrant's Name & Address GenMerica NA LLC % GHB Consulting, 1660 3 rd Ave SW, LeMars, IA 51031			Product Bifenthrin Technical		
ngredient bifenthrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite All	CHEMSICO A Division of United Industries Corp. PO Box 142642 St. Louis, MO 63114	Pay	
		Cite All	LESCO, Inc. 1385 E 36 th Street Cleveland, OH 44114	Pay	
		Cite All	ADAMA Makhteshim Ltd. Makhteshim-Agan of North America, 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604	Pay	
		Cite All	Loveland Products, Inc. PO Box 1286 Greeley, CO 80632	Pay	
		Cite All	Howard Fertilizer & Chemical Co Inc Registrations by Design, Inc. PO Box 1019 Salem, VA 24153	Pay	
		Cite All	Albaugh, LLC PO Box 2127 Valdosta, GA 31604	Pay	
signature			Name and Title Glenda Haage, Regulatory Agent		Date 2017-07-12

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		DATA MATRIX			
Date 2017-07-12	ate 2017-07-12		EPA Reg. No./File Symbol 91640-xx	Page 6 of 11	
Applicant's/Registrant's Name & Address GenMerica NA LLC % GHB Consulting, 1660 3 rd Ave SW, LeMars, IA 51031		Product Bifenthrin Technical			
ngredient bifenthrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite All	BASF Sparks LLC PO Box 13528 Research Triangle Park, NC 27709	Pay	
		Cite All	Control Solutions, Inc. 5903 Genoa Red Bluff Road Pasadena, TX 77507	Pay	
		Cite All	Arizona Chemical Group, Inc. PYXIS Regulatory Consulting, Inc. 4119 136 th St., NW Gig Harbor, WA 98332	Pay	
		Cite All	Valent U.S.A. LLC 1600 Riviera Ave, Ste 200 Walnut Creek, CA 94596	Pay	
		Cite All	Pyrethroid Working Group c/o Landis International, Inc. PO Box 5136 Valdosta, GA 31603	Pay	
		Cite All	Makhteshim Agan of North America Inc d/b/a ADAMA 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604	Pay	71.0-0-1
Signature Name and Title Glenda Haage, Regulatory Ager		Name and Title Glenda Haage, Regulatory Agent		Date 2017-07-12	

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		DATA MATRIX					
Date 2017-07-12	ate 2017-07-12		EPA Reg. No./File Symbol 91640-xx	Page 7 of 11			
Applicant's/Registrant's Name & Address GenMerica NA LLC % GHB Consulting, 1660 3 rd Ave SW, LeMars, IA 51031			Product Bifenthrin Technical				
ngredient bifenthrin							
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note		
		Cite All	ARYSTA LifeScience North America LLC 15401 Weston Pakrway, Suite 150 Cary, NC 27513	Pay			
		Cite All	Spray Drift Task Force McKenna, Long & Aldridge LLP 1900 K Street, NW Washington, DC 20006	Pay			
		Cite All	Bengal Products, Inc. 13739 Airline Hwy Baton Rouge, LA 70817	Pay			
		Cite All	United Phosphorus, Inc 630 Freedom Business Ctr, Ste 402 King of Prussia, PA 19406	Pay			
		Cite All	Outdoor Residential Exposure TF Beveridge & Diamond, P.C. 1350 I Street, NW Washington, DC 20005	Pay			
		Cite All	Agricultural Reentry Task Force Beveridge & Diamond, P.C. 1350 I Street, NW Washington, DC 20005	Pay			
signature Daniela Herange			Name and Title Glenda Haage, Regulatory Agent		Date 2017-07-12		

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		DATA MATRIX			
ate 2017-07-12			EPA Reg. No./File Symbol 91640-xx	Page 8 of 11	
Applicant's/Registrant's Name & Address GenMerica NA LLC % GHB Consulting, 1660 3 rd Ave SW, LeMars, IA 51031			Product Bifenthrin Technical		
ngredient bifenthrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite All	Sapstain Industry Group (SIG) Janssen PMP 1125 Trenton-Harbourton Rd. Titusville, NJ 09560	Pay	
		Cite All	Non-Dietary Exposure Task Force CSPA/PIR 1667 K Street NW, Suite 300 Washington, DC 20006	Pay	
		Cite All	NISSO TM LLC 88 Pine Street, 14 th Floor New York, NY 10005	Pay	
		Cite All	UNIVAR Environmental Sciences Building 1, Suite 210 115 Obtuse Hill Road Brookfield, CT 06804	Pay	
		Cite All	FIFRA Endangered Species Task Force c/o Compliance Services International 7501 Bridgeport Way, W Lakewood, WA 98499	Pay	
		Cite All	Residential Exposure Joint Venture CSPA/PIR 1667 K Street, NW, Suite 300 Washington, DC 20006	Pay	
Signature Lively Honge			Name and Title Glenda Haage, Regulatory Agent		Date 2017-07-12

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Washington, DC 20460. Do not	send the form to this address.				
		DATA MATRIX			
Date 2017-07-12 Applicant's/Registrant's Name & Address GenMerica NA LLC % GHB Consulting, 1660 3 rd Ave SW, LeMars, IA 51031		EPA Reg. No./File Symbol 91640-xx	Page 9 of 11		
			Product Bifenthrin Technical		
ngredient bifenthrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite All	ATEX, Inc. Landis International, Inc. PO Box 5126, 3185 Madison Highway Valdosta, GA 31603	Pay	
		Cite All	Agricultural Handler Exposure TF Johnson Management & Consulting LLC PO Box 509, 1720 Prospect Drive Macon, MO 63552	Pay	
		Cite All	Osmose Utilities Services, Inc. 635 Hwy 74 S Peachtree City, GA 30269	Pay	
		Cite All	ENSYSTEX II, Inc. PYXIS Regulatory Consulting, Inc. 4110 136 th Street, NW Gig Harbor, WA 98332	Pay	
		Cite All	Sharda Crop Chem Limited Wagner Regulatory Associates Inc. PO Box 640 Hockessin, DE 19707	Pay	
		Cite All	Winfield Solutions, LLC PO Box 64589 1080 County Rd F W, MS5705 St. Paul, MN 55164	Pay	
Signature Showle though			Name and Title Glenda Haage, Regulatory Agent		Date 2017-07-12

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Date 2017-07-12 Applicant's/Registrant's Name & Address GenMerica NA LLC % GHB Consulting, 1660 3 rd Ave SW, LeMars, IA 51031		EPA Reg. No./File Symbol 91640-xx	Page 10 of 11		
		Product Bifenthrin Technical			
ngredient bifenthrin				<u></u>	,,,,,,
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite All	Tacoma Ag, LLC PYXIS Regulatory Consulting, Inc. 4110 136 th Street, Ct NW Gig Harbor, WA 98332	Pay	
		Cite All	Sharda USA LLC Wagner Regulatory Associates, Inc. PO Box 640 Hockessin, DE 19707	Pay	
		Cite All	ENSYSTEX IV, Inc. PYXIS Regulatory Consulting, Inc. 4110 136 th Street Gig Harbor, WA 98332	Pay	
		Cite All	Wet & Forget USA Ltd. Lewis & Harrison, LLC 122 C Street, NW, Suite 505 Washington, DC 20001	Pay	
-		Cite All	Generic Endangered Species TF PYXIS Regulatory Consulting, Inc. 4110 136 th Street, NW Gig Harbor, WA 98332	Pay	
		Cite All	Kaizen Technologies, LLC Lighthouse Product Services 3720 Woodhaven Lane Johnston, CO 80534	Pay	
Signature Silved Hoogs			Name and Title Glenda Haage, Regulatory Agent		Date 2017-07-12

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_		DATA MATRIX			
Date 2017-07-12 AppliCanl's/Registrant's Name & Address GenMerica NA LLC % GHB Consulting, 1660 3rd Ave SW, LeMars, IA 51031		EPA Reg. No./File Symbol 91640-xx	Page 11 of 11		
		144.	Product Bifenthrin Technical		
Ingredient bifenthrin			I		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite All	Bifenthrin Task Force Steering Committ CSPA/PIR 1667 K Street, NW, Suite 300 Washington, DC 20006	Pay	
		Cite All	VIVE Crop Protection, Inc. OMC Ag Consulting 828 Tanglewood Lane East Lansing, MI 48823	Pay	
		Cite All	Liberty Crop Protection, LLC 4850 Hahns Peak Drive, Suite 200 Loveland, CO 80538	Pay	
		Cite All	Prime Source, LLC Wagner Regulatory Associates, Inc. PO Box 640 Hockessin, DE 19707	Pay	
		Cite All	GenMerica NA LLC GHB Consulting 1660 3 rd Ave SW LeMars, IA 51031	Pay	
		Cite All	TEVRA Brands, LLC 9100 F Street, Suite 200 Omaha, NE 68127	Pay	
Signature			Name and Title Glenda Haage, Regulatory Agent		Date 2017-07-12

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Fee for Service

{990179L~

This package includes the following	for Division
New RegistrationAmendment✓ Studies?Fee Waiver?	○ AD ○ BPPD ○ RD
□ volpay % Reduction:	Risk Mgr. 3
Receipt No. S- EPA File Symbol/Reg. No. Pin-Punch Date:	990179 91640- <u>T</u> 8/9/2016
This item is NOT subject t	o FFS action.
Action Code: Requested: R334 Granted: R334 Amount Due: \$ 19,838	Parent/Child Decisions:
■ Inert Cleared for Intended Use	Uncleared Inert in Product
Reviewer: () () () () () () () () () (Date: 10-1906-2016



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

August 11, 2016

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OPP Decision Number: D-520227

EPA File Symbol or Registration Number: 91640-I Product Name: BIFENTHRIN TECHNICAL

EPA Receipt Date: 09-Aug-2016 EPA Company Number: 91640

Company Name: GENMERICA NA LLC.

GLENDA HAAGE GHB CONSULTING AGENT FOR GENMERICA NA LLC. 1660 3RD AVE SW LEMARS, IA 51031-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R334

NEW PRODUCT; MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OF THE ACTIVE INGREDIENT; REQUIRES SCIENCE DATA REVIEW; NEW PHYSICAL FORM; SELECTIVE DATA CITATION;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff

Information Technology & Resources Management Division

Glenda Haage

From:

notification@pay.gov

Sent:

Thursday, July 28, 2016 9:50 AM

To:

Glenda Haage

Subject:

Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. To confirm that the payment processed as expected, you may refer to your bank statement on the scheduled payment date. If you have any questions or wish to cancel this payment, you will need to contact the agency you paid at your earliest convenience.

If you chose the option to receive payment reminders in your user profile and this is a deferred or recurring payment, you will receive a reminder email several days before the payment is processed. You may change your payment reminder preferences and email address in your user profile at any time.

If you wish to cancel this transaction, log in to your account at https://www.pay.gov/ and choose the Pending tab of the Payment Activity page.

Application Name: PRIA Service Fees Pay.gov Tracking ID: 25T0RIU4 Agency Tracking ID: 75062170961

Account Holder Name: GenMerica NA LLC

Transaction Type: ACH Debit Transaction Amount: \$19,838.00 Payment Date: 07/29/2016 Account Type: Business Checking Routing Number: 075000022

Account Number: *********7907

Transaction Date: 07/28/2016 10:50:15 AM EDT

Total Payments Scheduled: 1

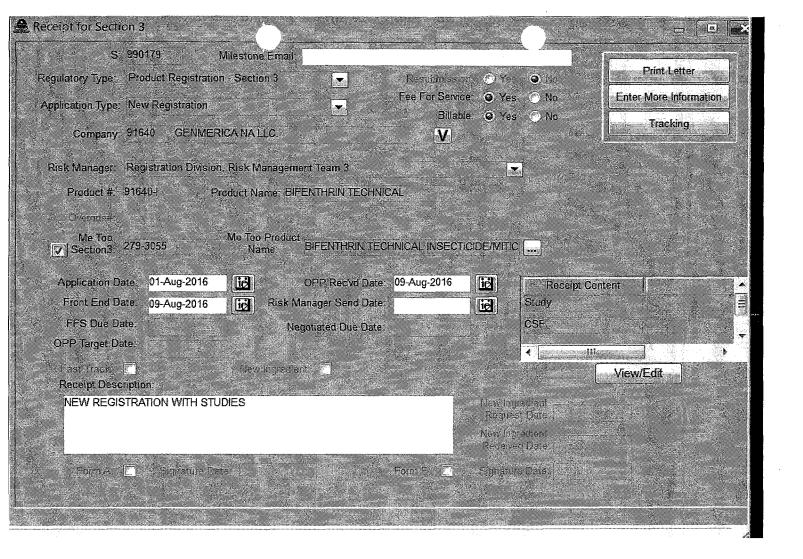
Frequency: OneTime

Registration Number:

Company Name: GenMerica NA LLC Company Number: 712-540-6290

Action Code: R334

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



PRIA 3 – 21 Day Content Screen Review Worksheet (EPA/OPP Use Only) September 2012

Expe	rts In-Processing Signature:	//-/6 ate	Fee I	Paid: Y	es	
EPA I	Reg. Number: 91640 – I EPA Receipt Date: 8–9	-16				
	Items for Review			Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete includitype	ng pac	kage	X		
2	Confidential Statement of Formula all boxes completed, form signated (EPA Form 8570-4)	nd	X			
2	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A) No Morts to Lunew	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-completed and signed (N/A if 100% repack)		X			
	Certificate and data matrix consistent					
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)				.	
	If applicable, is there a letter of Authorization for exclusive use onl	y				
4	Formulator's Exemption Statement (EPA Form 8570-27) compl signed (N/A if source is unregistered or applicant owns the technical		d			X
	Data Matrix (EPA Form 8570-35) both internal and external copie completed and signed (N/A if 100% repack)	es (<u>PR 9</u>	<u>98-5</u>)	ķ		
5	a) Selective Method (Fee category experts use)	yes X	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					-22.00
6	5 Copies of <u>Label</u> (<u>Electronic labels on CD</u> are encouraged and available)	nce is	X			
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, reduced risk rationale		×				
	Required Data and/or data waivers. See Footnote C.						
	a) List study (or studies) not included with application						
10							
			•				
Comm	Documentation Rasser Fa.1 Comments: All Required Forms complete						
	Inerts Pais or Fail - Technical, Water, Impunties Only, No Inerts to Review						
	PKN 11-03 (Pass) or Fail						
	PKN 11-03 (Pass) or faill -MRID: 499891 =05 no confidential attachment -submitter contacted 8/12						
	· issue corrected						
	Overall Status: Rasgor Fail						

Varner, Stephanie

From:

Glenda Haage <glenda@consultghb.com>

Sent:

Monday, August 15, 2016 11:55 AM

To:

Varner, Stephanie

Subject:

RE: Submission to EPA: BIFENTHRIN TECHNICAL (EPA Reg. No. 91640-I)

Attachments:

2016-07-07 Physical Chemical Report-Bifenthrin-

volume 5 (updated

2016-08-15 adding new confidentiality claim).pdf

Note new email address: glenda@consultghb.com Please update your records.

Glenda Haage GHB Consulting 1660 3rd ave SW LeMars, Iowa 51031 Phone: 712-540-6290

From: Varner, Stephanie [mailto:Varner.Stephanie@epa.gov]

Sent: Monday, August 15, 2016 9:19 AM
To: Glenda Haage <glenda@consultghb.com>

Subject: RE: Submission to EPA: BIFENTHRIN TECHNICAL (EPA Reg. No. 91640-I)

Hi Glenda,

That's perfect thanks! And I just noticed the mixed up subject line. Sorry about that! Copied it from another email and forgot to switch it.

Thanks again! Stephanie

From: Glenda Haage [mailto:glenda@consultghb.com]

Sent: Monday, August 15, 2016 9:19 AM

To: Varner, Stephanie < Varner. Stephanie@epa.gov >

Subject: RE: Submission to EPA: KILL'EM ALL (EPA Reg. No. 92138-R)

Stephanie,

After review, I see that the confidentiality claim is in error. GHB consulting cut and paste from the original study which is used for other countries. It should not have any claims. I will revise and send back to you this morning if that works? Glenda

Note new email address: glenda@consultghb.com Please update your records.

Glenda Haage GHB Consulting 1660 3rd ave SW LeMars, Iowa 51031 Phone: 712-540-6290 From: Varner, Stephanie [mailto:Varner.Stephanie@epa.gov]

Sent: Friday, August 12, 2016 11:02 AM

To: Glenda Haage <glenda@consultghb.com>

Subject: Submission to EPA: KILL'EM ALL (EPA Reg. No. 92138-R)

Dear Ms. Haage,

My name is Stephanie Varner, and I am a contractor with the EPA. I am contacting you in regards to your submissions in support of the product BIFENTHRIN TECHNICAL (EPA Reg. No. 91640-I). We have found a deficiency with the submissions that will need to be addressed:

1. Study 499891-05, "Determination of Physical-Chemical Properties of Bifenthrin", is unacceptable. When confidentiality is claimed, the confidential information must be removed to a confidential attachment. Please send a revised version of this study with a confidential attachment included.

Thank you!

Stephanie Varner

Contractor, US EPA 2777 S. Crystral Drive, S-4813 Arlington, VA 22202 (703) 347-0240

Email: varner.stephanie@epa.gov



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OFFICE OFPESTICIDE PROGRAMS REGISTRATION DIVISION

18/JUL/2017

MEMORANDUM

Subject: Name of Pesticide Product: Bifenthrin Technical

EPA Reg. No. /File Symbol: 91640-I

DP Barcode: Decision No: D435330 520227

Action Code:

R334

PC Code:

128825 (bifenthrin)

From:

Eugenia McAndrew, Biologist Tuyma McLindu Chemistry, Inerts and Toxicology Assessment Branch

Registration Division (7505P)

Through: P.V. Shah, PhD, Chief

pysherh. Chemistry, Inerts and Toxicology Assessment Branch

Registration Division (7505P)

To: Timothy Ciarlo, RM Team 03

Invertebrate and Vertebrate Branch 1

Registration Division (7505P)

Applicant: GenMerica NA, LLC

> c/o GHB Consulting 1660 3rd Avenue SW Lemars, IA 51031

FORMULATION FROM LABEL:

% by wt. Active Ingredient(s): 98.4 Bifenthrin

1.6 Other ingredients: 100.0 Total:

ACTION REQUESTED: Similarity determination for 91640-I, proposed product, and 279-3055, cited product.

BACKGROUND: GenMerica NA, LLC has applied for registration of Bifenthrin Technical, EPA File Symbol 91640-I, claiming similarity to Bifenthrin Technical, EPA Reg. No. 279-3055. Both products are technical grade for manufacturing use only. The submission includes a Basic CSF and Alternate CSF #1 dated July 31, 2016, label, data matrix and company letter.

The registrant is using the cite all method of data support to satisfy the acute toxicity data requirements. After searching the OPP electronic databases we were unable to locate any previous acute toxicity data or memos pertaining to EPA Reg. No. 279-3055.

RECOMMENDATIONS:

- 1. We compared the basic CSFs and labels of the proposed product, 91640-I, and the cited product, 279-3055, and determined that the two products are substantially similar.
- 2. Since we couldn't find an acute toxicity profile for the cited product, 279-3055, an acute tox profile for the proposed product, 91640-I, cannot be generated.
- 3. Based on the label for 279-3055, the signal word for 91640-I is "WARNING." We recommend that the proposed product use the same precautionary labeling as the cited product.
- 4. The proposed Basic CSF and Alternate CSF #1 submitted for 91640-I must be reviewed and accepted by the product chemists in the Chemistry, Inerts and Toxicology Assessment Branch.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460 OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DP BARCODE No.: D435329; FILE SYMBOL No.: 91640-I; PRODUCT NAME: Bifenthrin Technical;

DECISION No.:520227; PC Code(s): 128825; ACTION CODE: R334; FOOD Use: Yes:

COMPANY: GenMerica NA LLC

DATE:

May 5, 2017

SUBJECT:

Product Chemistry Review of "Bifenthrin Technical"

FROM:

Shyam Mathur, Ph. D.

Chemistry Team Leader

Chemistry, Inerts & Toxicology Assessment Branch (CITAB)/RD (7505P)

TO:

Timothy Ciarlo / Kable Davis, RM 03

I-V Branch 1 / RD (7505P)

REGISTRANT: GenMerica NA LLC MRID Numbers: 49989101 to 49989105

INTRODUCTION:

GHB Consulting on behalf of GenMerica NA LLC has submitted an application for the registration of the Bifenthrin technical product. The registration has submitted the basic CSF & and an alternate CSF #1 (both dated July 31, 2016) corresponding to two production sites, both located The registrant has certified that for both the production sites the same starting materials (830.1600) and the same production process (830.1620) are used. The both the proposed CSF's have been supported by the product chemistry data submitted with MRID Nos. 49989101 to 49989105.

Proposed basic CSF dated July 31, 2016:

Production site

Supporting Data - MRID No. 49989102 (5 batch analysis)

Proposed alternate CSF #1 dated July 31, 2017

Production site -

Supporting Data - MRID No. 49989103 & 49989104 (5 batch analysis).

CITAB has been asked to determine the acceptability of the proposed basic & alternate CSF's and the supporting product chemistry data.

SUMMARY OF FINDINGS:

1. Group A guidelines:

830.1550 (product identity & composition)

The submitted data are acceptable. Active ingredient and process-related impurities were adequately described (MRID 49989101). The proposed nominal concentration of the active ingredient for both the production sites were determined to be 98.7% which is also proposed product label claim nominal concentration. The results are based on the preliminary analysis conducted on the technical product from the two sites. The submitted data satisfy the data requirements for 40CFR 158.320.

DP BARCODE No.: <u>D435329</u>; FILE SYMBOL No.: <u>91640-I</u>; PRODUCT NAME: <u>Bifenthrin Technical</u>; DECISION No.: <u>520227</u>; PC Code(s): <u>128825</u>; ACTION CODE: R334; FOOD Use: Yes

830.1600 (description of materials used to produce the product)

The product chemistry data submitted for the guideline 830.1600 (description of starting materials) are acceptable. The registrant has submitted MSDS's for all the starting materials used at both the sites for the production of bifenthrin technical under MRID No. 49989101. Both the sites use the same starting materials as certified by the applicant. The information presented meets the data requirements for 40CFR 158.325.

830.1620 (description of production process)

The product chemistry data submitted data for the guideline 830.1620 (description of production process) are acceptable. The technical bifenthrin was produced at the two sites following the same procedure which is batch process that includes

The registrant has provided description of the production process, flow charts, chemical reactions pathways, and quality control measures were provided in MRID 49989101. The information presented meets the data requirements for 40CFR 158.330.

830.1670 (discussion on the formation of impurities)

The product chemistry data submitted for the guideline 830.1670 (discussion on the formation of

impurities) are acceptable. Detailed information regarding the origins of impurities was provided (MRID 49989101). Potential impurities were identified and quantified as part of the five-batch analysis for both the sites independently. The registrant has reported only impurity present at the concentrations at the levels of > 0.1% in the proposed basic CSF and impurities in the alternate CSF # 1 based on the five batch analysis. The impurities identified at the alternate production site are not expected to be of tox concern based on their chemical structure and the levels of low concentrations. The information presented satisfy the data requirements for 40CFR 158.340.

830.1700 (preliminary analysis)

The submitted data are acceptable. The five batch analysis for the performed by AgriFor Scientific Private Ltd., North Ryde, Australia. Five batches were analyzed for the determination of bifenthrin (also cis/trans) and related significant impurities by using validated GC-FID method with external standard calibration. The significant impurities were identified by GC/MS method. The details of the method have been submitted [MRID No. 49989102].

The preliminary analysis for a control (alternate CSF #1) was performed by Nutrichem Laboratory, Haidian District, Beijing, China. The active ingredient & the significant impurities were determined by validated HPLC-UV with external standard calibration [MRID No. 49989103].

The identification of the active ingredient bifenthrin in Bifenthrin TGAI product was performed by using HPLC-DAD-MS and NMR spectra respectively against bifenthrin analytical standard. The identification for the in the test item Bifenthrin TGAI by retention time, the major shape of the UV spectra and major mass signals of the mass spectra was performed by using HPLC-DAD and HPLC-MS respectively against corresponding analytical standard [MRID No. 49989104].

The data submitted satisfy the data requirements of 40CFR§158.345

Manufacturing process information may be entitled to confidential treatment

2

^{*}Product ingredient source information may be entitled to confidential treatment*

DP BARCODE No.: <u>D435329</u>; FILE SYMBOL No.: <u>91640-I</u>; PRODUCT NAME: <u>Bifenthrin Technical</u>; DECISION No.:<u>520227</u>; PC Code(s): <u>128825</u>; ACTION CODE: <u>R334</u>; FOOD Use: Yes

830.1750 (certified limits)

The product chemistry data submitted for the guideline 830.1750 satisfy the data requirements of 40CFR§158.350. The registrant has proposed the nominal concentration of 98.7% for the active ingredient bifenthrin. The registrant has proposed standard certified limits for the Al whereas the proposed certified limits for the impurities are based on the five batch analysis. The proposed certified limits are in compliance with 40CFR158.350 [MRID No. 49989101].

830.1800 (enforcement analytical method)

The active ingredient bifenthrin technical was determined by HPLC-UV method with UV detector operating at 245 nm or by GC-FID method and in both the analytical methods the quantification was done by external standard technique. The method was validated for selectivity, linearity, and recovery. The HPLC-UV method is used to determine cis-trans ratio of bifenthrin. The information presented meets the data requirements for 40 CFR §158.355 [MRID No. 49989101].

2. The registrant has submitted the physical-chemical characteristics for the technical bifenthrin produced at (basic CSF) in China. The product chemistry data submitted for Group B guidelines (physical-chemical properties) satisfy the data requirements of 40CFR§158.310.

CONCLUSIONS:

The CITAB has reviewed the proposed basic & alternate CSF #1 and the supporting group A & group B product chemistry data for "Bifenthrin Technical" and has concluded that:

- The product chemistry data submitted for guidelines 830.1550 (product identity & composition), 830.1600 (description of materials used to produce the product), 830.1620 (description of the production process), 830.1670 (discussion of the formation of impurities), 830.1700 (preliminary analysis for both sites) and 830.1800 (enforcement analytical method) are acceptable.
- 2. The proposed basic CSF (dated July 31, 2016; and the alt CSF #1 (dated July 31, 2016; are acceptable and are supported by respective five batch analyses.
- 3. The group B (physical-chemical characteristics) product chemistry data submitted for the Bifenthrin technical produced at (basic CSF) are acceptable.
- 4. The registrant has identified additional impurities in the proposed alternate CSF #1 in very small amounts. According to the toxicologist of CITAB, these impurities are very similar in chemical structure to the parent compound and their toxicity will be very similar to or less than the parent compound. Therefore, it is expected that the presence of these impurities in small concentrations will not have any adverse health & environmental effects.

DP BARCODE No.: <u>D435329</u>; FILE SYMBOL No.: <u>91640-I</u>; PRODUCT NAME: <u>Bifenthrin Technical</u>; DECISION No.: <u>520227</u>; PC Code(s): <u>128825</u>; ACTION CODE: <u>R334</u>; FOOD Use: <u>Yes</u>

830.1550. Product identity & composition: (MRID No. 49989101, -04)

Active Ingredient:	Bifenthrin			
Empirical Formula:	C ₂₃ H ₂₂ CIF ₃ O ₂			
Molecular Weight:	422.9			
CAS Registry Number:	82657-04-3			
IUPAC Name:	2-methylbiphenyl-3-ylmethyl (<i>Z</i>)-(1 <i>RS</i> ,3 <i>RS</i>)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate <i>Roth:</i> 2-methylbiphenyl-3-ylmethyl (<i>Z</i>)-(1 <i>RS</i>)- <i>cis</i> -3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate			
Structure Formula:	and CI STATE OF THE STATE OF TH			

DP BARCODE No.: <u>D435325</u>, £ILE SYMBOL No.: <u>91640-l</u>; PRODUCT NaME: <u>Bifenthrin Technical</u>; DECISION No.: <u>520227</u>; PC Code(s): <u>128825</u>; ACTION CODE: <u>R334</u>; FOOD Use: <u>Yes</u>

Table 1. Manufacturing and Impurity Data for "Bifenthrin Technical"				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	49989101	Α	See summary of findings
830.1600	Description of materials used to produce the product	49989101	Α	See summary of findings
830.1620	Description of production process	49989101	Α	See summary of findings
830.1670	Discussion of formation of impurities	49989101	Α	See summary of findings
830.1700	Preliminary analysis	49989102 49989103 49989104	Α	See summary of findings
830.1750	Certified limits	Basic CSF (7-31-2017)	Α	The proposed upper limit & lower limits of the AI is based on standard certified limits whereas for the impurities the limits were based on five batch analysis. The proposed certified limits for the impurities are based on the results of 5 batch analysis. The proposed NC is 98.7% which is also product label claim nominal concentration
830.1800	Enforcement analytical method	49989102	Α	See summary of findings

 $A = Acceptable; \ N = Unacceptable \ (see \ Deficiency); \ N/A = Not \ Applicable; \ G = Data \ gap; \ I = In \ progress; \ U = Up-grade \ (additional \ information \ required);$

DP BARCODE No.: <u>D435325</u>, £ILE SYMBOL No.: <u>91640-I</u>; PRODUCT N.: <u>ME</u>: <u>Bifenthrin Technical</u>; DECISION No.: <u>520227</u>; PC Code(s): <u>128825</u>; ACTION CODE: <u>R334</u>; FOOD Use: <u>Yes</u>

830 Series Subgroup B (Physical-Chemical Properties)

GLN	Requirement	MRID	Status	Result or Deficiency	
830.6302	Color	49989105	Α	White	
830.6303	Physical state	49989105	А	Solid (Fine Powder) @ 20°C	
830.6304	Odor	49989105	Α	Odorless	
830.6313 830.6317	Stability to normal and elevated temperatures, metals, and metal ions Accelerated storage stability	49989105	А	TS stable at RT & 54°C The Test Item was considered to be stable in terms of Active Ingredient content when exposed to iron powder, aluminium powder, and the corresponding acetates.	
830.6314	Oxidation/reduction: chemical incompatibility	49989105	А	Test substance was found to be compatible with water, monoammonium phosphate, Fe powder, 0.01M KMnO ₄ and kerosene.	
830.6315	Flammability		NA		
830.6316	Explodability		NA		
830.6317	Accelerated storage stability	49989105	Α	The Test Item is stable for 14 Days at room Temperature and at 54±2°C when stored in glass containers.	
830.6319	Miscibility		NA		
830.6320	Accelerated Corrosion characteristics	49989105	A	No corrosion on the glass containers after storage for 14 days at room temperature and 54±2°C	
830.7000	рН	49989105	Α	6.96 at 19.5°C	
830.7050	UV/Visible absorption	49989105	Α	Neutral (λ=205.0 log(έ)=4.76 Acidic (λ)=208.5 log(έ)=4.71 Basic (λ)=205.0 log(έ)=5.06	
830.7100	Viscosity		NA		
830.7200	Melting point	49989105	Α	69.6°C	
830.7220	Boiling point	49989105	NA		
830.7300	Density	49989105	Α	Pour Density (g/mL) 0.32 Tap Density (g/mL) 0.45	
830.7370	Dissociation constants in water (DC)	49989105	A	Does not dissociate	
830.7550	Partition coefficient	49989105	Α	7.42 (by HPLC)	
830.7840	Water solubility	49989105	Α	Water = <0.1 mg/L (pH 6.87) @ 22°C MeOH = 50.1 g/L @ 22°C Hexane = 154.9 g/L @ 22°C	
830.7950	Vapor pressure*	49989105	A	0.20 mPa @ 20°C	

 $A = Acceptable; \ N = unacceptable \ (see \ Deficiency); \ N/A = Not \ Applicable; \ G = Data \ gap; \ I = In \ progress; \ U = Up-grade \ (additional \ information \ required); \ W = waivers$

DP BARCODE No.: D43532b, ALE SYMBOL No.: 91640-I; PRODUCT NaME: Bifenthrin Technical;

DECISION No.:520227; PC Code(s): 128825; ACTION CODE: R334; FOOD Use: Yes

830.1800 (enforcement analytical method)

(MRID No. 49989102)

The active ingredient bifenthrin was determined by GC using FID detector. Quantitation is through external standard calibration curve. The method was validated for linearity (up to 0.603 mg/ml & correlation coefficient of 0.999819) & precision (recovery > 100% with RSD 0.44%).

Equipment

Instrument: GC-FID 2010 equipped with AOC-20i Autosampler Column: BP 1, 28 m x 0.32 mm id x 0.25 µm film thickness (SGE)

Injector temperature: 270°C

Temperature program: 170°C for 0 min., then 7.0°C/min to 300°C hold for 6.42 min.

Injection volume: 1 µL

Carrier gas: Helium 30 cm/sec Detector temperature: 300 °C

Run time: 25 minutes

The GC-FID method was validated for specificity, reproducibility and system precision,

Five batches of technical grade Bifenthrin (GAFS13/4376 – GAFS13/4380) were analysed by GC-FID.

The samples were analysed for the content of the active ingredient utilising a method of analysis developed at the Test Facility. The analysis parameters used to evaluate the active content were designed to satisfy the batch analysis requirements for technical grade active constituent (TGAC) as per WHO/FAO specifications.

The results are summarized in the table given below:

Sample no.	Client no.	Bifenthrin (g/kg)
GAF\$13/4376	20130662	986.1
GAF\$13/4377	20130473	986.9
GAF\$13/4378	20130704	987.3
GAF\$13/4379	20130618	987.8
GAF\$13/4380	20130537	985.6
	Mean	986.7
	Std Dev	0.9
	% RSD	0.1

DP BARCODE No.: D435325, FILE SYMBOL No.: 91640-I; PRODUCT NaME: Bifenthrin Technical;

DECISION No.: 520227; PC Code(s): 128825; ACTION CODE: R334; FOOD Use: Yes

Analysis of Bifenthrin for Cis- & trans- isomers by HPLC

The cis & trans isomers were separated on the reversed HPLC column and the content of cis & trans isomers was determined by calculating area percent ratio of separated peaks. Quantitation was done by external standard curve. Sample solutions of the test substance and standard substance were prepared in acetonitrile with known concentrations and analyzed on HPLC using following parameters:

Instrument: LC-10ADVP, SIL-10ADVP Autosampler, SPD-M10A VP PDA

Column: Wakasil C 18, 4.0 x 250 ml (SGE) Mobile phase: acetonitrile: water (75:25% v/v)

Flow rate: 1.0 ml/min Injection volume: 1µ

Column temperature: 35°C

Detector: PDA operating at 203 nm

Run time: 42 minutes

Retention times: Trans isomer – 23.19 min; Cis isomer – 25.91 min

Results are summarized in the following table:

Sample no.	Conc. (mg/l)	Rt Trans- isomer (min.)	Area Trans- isomer (mAUsec)	Rt Cis isomer (min.)	Area Cis- isomer (mAUsec)	Trans- : Cis isomer (%)
Bifenthrin	995.3	23.172	248599	25.880	60411316	0.4:99.6
4376	1030	23.196	67855	25.912	61129057	0.1:99.9
4377	1170	22.972	65665	25.708	62061812	0.1:99.9
4378	1120	23.224	70606	25.916	61850782	0.1:99.9
4379	1050	23.000	62244	25.656	60118899	0.1:99.9
4380	1080	23.168	74537	25.880	63397494	0.1:99.9





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 17, 2017

Glenda Haage Agent GenMerica NA, LLC 1660 3rd Ave SW LeMars, IA 51031

Subject: R334 New Bifenthrin Product

EPA File Symbol: 91640-I

Product Name: Bifenthrin Technical Application Dated: July 31, 2016 PRIA Due Date: July 31, 2017 Decision Number: 520227

Dear Ms. Haage:

The Agency has completed its review and assessment of your application pursuant to Section 33(b)(3) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended by the Pesticide Registration Improvement Extension Act of 2012. The Agency has made a predecisional determination that your application cannot be approved unless revisions are made to the label. The necessary label changes are specified on the attached label. This version of the label was also emailed to you on July 13, 2017.

Since there is limited time before the PRIA Decision Due Date expires, it is important to discuss any objections you have to these changes immediately and whether you will need to submit additional data for review. If these discussions determine that submitting data will be necessary, the PRIA decision due date may need to be renegotiated to allow sufficient time to address and resolve such differences. If the PRIA Decision Due Date is not renegotiated, and the label issues are not resolved before the PRIA Decision Due Date, the Agency will send a follow-up letter that will represent the Agency's decision to close out the PRIA decision review time. The follow-up letter will provide the following three options for continuing the review of the application:

(a) Applicant agrees to all of the terms associated with the draft accepted label as revised by the Agency and requests that it be issued as the accepted final Agency-stamped label; or

Page 2 of 2 EPA File Symbol: 91640-I

Decision No. 520227

- (b) Applicant does not agree to one or more of the terms of the draft accepted label as revised by the Agency and requests additional time to resolve the difference(s); or
- (c) Applicant withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee.

If the applicant informs EPA that it has concerns as described under (b) above, the applicant will have up to 30 calendar days from the date of that follow-up letter to reach agreement with the Agency on the final version of the label that the Agency will accept. If an agreement cannot be reached within those 30 days, EPA would intend to proceed with denial of the application.

If the applicant agrees to all of the terms of the accepted label as described in (a) above, or if the applicant and EPA resolve any differences as described in (b), the applicant must submit a revised label to EPA. EPA will then provide an accepted final Agency stamped label to the applicant within 2 business days following the applicant's written electronic confirmation of agreement to the Agency including the revised label to be stamped.

If you have any questions, please contact Tim Ciarlo at 703-347-8082 or via email at Ciarlo. Timothy@epa.gov.

Sincerely,

Elizabeth Fertich

Acting Product Manager 03

Invertebrate & Vertebrate Branch 1

Registration Division (7505P)

Office of Pesticide Programs

Enclosure: Proposed label containing EPA edits sent via email July 13, 2017



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

May 4, 2017

OPP Decision Number: 520227

Glenda Haage GHB Consulting (Agent) GenMerica NA, LLC 1660 3rd Ave SW LeMars, IA 51031

Subject:

Application Deficiency

Product Name:

Bifenthrin Technical

EPA File Symbol:

91640-I

Application Date:

July 31, 2016

EPA Receipt Date:

August 9, 2016

Dear Ms. Haage:

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105. Please ensure that you consider each of the options below in determining how and when you respond to this letter.

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time are:

 The six acute toxicity studies (MRIDs 453536-02 through -07) listed on the data matrix dated July 7, 2016 cannot support the proposed product 91640-I. These studies pertain to an end use product which contains 1.1% bifenthrin. The proposed product 91640-I contains 98.7% bifenthrin and must be supported by acute toxicity studies conducted with Page 2 of 2 EPA Reg. No. 91640-I Decision No. 520227

test substances which match the proposed product in active ingredient composition and concentration.

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

Please respond to this letter within 75 days of the stamped date by contacting Tim Ciarlo or Kable Bo Davis by telephone at 703-347-8082 and 703-306-0415, respectively, or by e-mail at Ciarlo.Timothy@epa.gov or Davis.Kable@epa.gov during the hours of 8:00 am to 4:30 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Kable Bo Davis, Product Manager 3 Invertebrate and Vertebrate Branch 1 Registration Division (7505P) Office of Pesticide Programs

Enclosure

Ciarlo, Timothy

From:

Glenda Haage < glenda@consultghb.com>

Sent:

Wednesday, July 19, 2017 10:13 AM Resulainission # 8

To:

Ciarlo, Timothy

Cc:

Fertich, Elizabeth

Subject:

RE: BIfenthrin 91640-I

Attachments:

2017-07-19 Bifenthrin Tech MUP label (4).pdf

Here you go, if you need more changes, don't hesitate to ask.

Glenda

Note new email address: glenda@consultghb.com Please update your records.

Glenda Haage GHB Consulting 1660 3rd ave SW LeMars, Iowa 51031 Phone: 712-540-6290

From: Ciarlo, Timothy [mailto:Ciarlo.Timothy@epa.gov]

Sent: Wednesday, July 19, 2017 7:59 AM

To: Glenda Haage <glenda@consultghb.com>
Cc: Fertich, Elizabeth <fertich.elizabeth@epa.gov>

Subject: RE: Blfenthrin 91640-I

Hi Glenda,

I feel silly asking you to do this, but we've had labels fail our QA/QC screen for it... Could you add a number 1 to the first page? If the other pages are numbered, they all should be numbered. Other than that, it looks good to go.

Thanks for your patience.

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1

Email: Ciarlo.Timothy@epa.gov

Phone: 703-347-8082

From: Glenda Haage [mailto:glenda@consultghb.com]

Sent: Tuesday, July 18, 2017 4:55 PM Resubmission #7

To: Ciarlo, Timothy < Ciarlo. Timothy@epa.gov > Cc: Fertich, Elizabeth < fertich.elizabeth@epa.gov >

Subject: RE: Blfenthrin 91640-I

Hi Tim,

I think I have everything changed.

Please let me know if more are needed.

Best regards, Glenda

Note new email address: glenda@consultghb.com Please update your records.

Glenda Haage GHB Consulting 1660 3rd ave SW LeMars, Iowa 51031 Phone: 712-540-6290

From: Ciarlo, Timothy [mailto:Ciarlo.Timothy@epa.gov]

Sent: Tuesday, July 18, 2017 2:56 PM

To: Glenda Haage <glenda@consultghb.com> **Cc:** Fertich, Elizabeth <fertich.elizabeth@epa.gov>

Subject: RE: Bifenthrin 91640-I

Hi Glenda,

It's been nice working with you as well. We're almost there!

One super tiny comment in the attached PDF, but now is the time to fix it. Please make that change and send over a revised label.

I've also attached the similarity review for your records. Please let me know if you have any questions or concerns.

Kind Regards,

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1

Email: Ciarlo.Timothy@epa.gov

Phone: 703-347-8082

From: Glenda Haage [mailto:glenda@consultghb.com]

Sent: Monday, July 17, 2017 5:30 PM, Resubmission # 6

To: Ciarlo, Timothy < <u>Ciarlo: Timothy@epa.gov</u>>

Subject: RE: Blfenthrin 91640-I

Tim,

Here is the label, I believe she has made the changes you requested. Any uses that are on the label are either on FMC's or Sharda's.

Let me know if you have questions or changes.

It has been nice working with you!

Glenda

Note new email address: glenda@consultghb.com Please update your records.

Glenda Haage GHB Consulting 1660 3rd ave SW LeMars, Iowa 51031

Phone: 712-540-6290

From: Ciarlo, Timothy [mailto:Ciarlo.Timothy@epa.gov]

Sent: Monday, July 17, 2017 1:53 PM

To: Glenda Haage <glenda@consultghb.com>

Cc: Fertich, Elizabeth < fertich.elizabeth@epa.gov >; Davis, Kable < Davis.Kable@epa.gov >

Subject: RE: Blfenthrin 91640-I

Hi Glenda,

The PRIA due date for this action is 7/31/17. Since today is the predecisional due date, we are sending a predecisional letter which references our label comments from last Thursday. Please confirm receipt of this letter by replying to this email.

Please let me know if you have any questions. As we talked about this morning, I'll stand by for your revised label, and I will send you the similarity determination from tox as soon as I receive it.

Kind Regards,

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1

Email: Ciarlo.Timothy@epa.gov

Phone: 703-347-8082

From: Glenda Haage [mailto:glenda@consultghb.com]

Sent: Friday, July 14, 2017 4:19 PM Resubmission # 5

To: Ciarlo, Timothy < Ciarlo. Timothy@epa.gov>

Subject: RE: Blfenthrin 91640-I

Well, I don't know what happened as I changed that myself yesterday, must not have saved it right....grrrr.....

Please find attached with cite all.

Thanks for your patience.

Note new email address: glenda@consultghb.com Please update your records.

Glenda Haage GHB Consulting 1660 3rd ave SW LeMars, Iowa 51031 Phone: 712-540-6290

From: Ciarlo, Timothy [mailto:Ciarlo.Timothy@epa.gov]

Sent: Friday, July 14, 2017 3:13 PM

To: Glenda Haage <glenda@consultghb.com>

Subject: RE: Blfenthrin 91640-I

Hi Glenda,

It looks good except you've still got "site" instead of "cite."

Tim

From: Glenda Haage [mailto:glenda@consultghb.com]

Sent: Friday July 14, 2017 4:03 PM) Resubmission # 4

To: Ciarlo, Timothy < Ciarlo: Timothy@epa.gov>

Subject: RE: Blfenthrin 91640-l

Tim,

Attached is the updated matrix.

Thanks. Glenda

Note new email address: glenda@consultghb.com Please update your records.

Glenda Haage GHB Consulting 1660 3rd ave SW LeMars, Iowa 51031

Phone: 712-540-6290

From: Ciarlo, Timothy [mailto:Ciarlo.Timothy@epa.gov]

Sent: Thursday, July 13, 2017 1:07 PM

To: Glenda Haage <glenda@consultghb.com>

Cc: Fertich, Elizabeth <fertich.elizabeth@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>

Subject: RE: Blfenthrin 91640-I

Hi Glenda,

The product chemistry MRIDs should be listed next to their corresponding Guidelines. Pages 5 and 6 of the chem review should help you with this. Please note that the product chem MRIDs you'll need to include are 499891-01 through -05, not 453536-02 through -07.

The password for the chem review is GenMericaBifenthrin.

I have also attached some label comments. Please respond back with a revised label at your earliest convenience. Most of my comments are questions which may not require changes. Please let me know if anything is unclear.

Regards,

From: Glenda Haage [mailto:glenda@consultghb.com]

Sent: Thursday, July 13, 2017 12:09 PM

To: Ciarlo, Timothy < Ciarlo. Timothy@epa.gov>

Subject: RE: Blfenthrin 91640-I

Is it okay if I just type 453536-02 through -07 in both of those boxes?

Note new email address: glenda@consultghb.com Please update your records.

Glenda Haage GHB Consulting 1660 3rd ave SW LeMars, Iowa 51031 Phone: 712-540-6290

From: Ciarlo, Timothy [mailto:Ciarlo.Timothy@epa.gov]

Sent: Thursday, July 13, 2017 9:36 AM

To: Glenda Haage <glenda@consultghb.com>

Subject: RE: Bifenthrin 91640-I

Thanks, Glenda. I'll make comments on it and get back to you as soon as possible. As requested, please see the product chem review, attached. I'll send the P/W in a follow-up email. The product chem MRIDs weren't referenced in the 75-day letter from a few months ago. I did mention them briefly in an email from May (also attached).

Please let me know if you have any questions.

Thanks,

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1

Email: Ciarlo.Timothy@epa.gov

Phone: 703-347-8082

From: Glenda Haage [mailto:glenda@consultghb.com]

Sent: Thursday, July 13, 2017 10:28 AM

To: Ciarlo, Timothy < Ciarlo. Timothy@epa.gov>

Subject: RE: Blfenthrin 91640-I

Tim,

Here is the labeling. Thx.

Glenda

Note new email address: glenda@consultghb.com Please update your records.

Glenda Haage GHB Consulting 1660 3rd ave SW LeMars, lowa 51031 Phone: 712-540-6290

From: Ciarlo, Timothy [mailto:Ciarlo.Timothy@epa.gov]

Sent: Thursday, July 13, 2017 8:28 AM

To: Glenda Haage <glenda@consultghb.com>

Subject: RE: Blfenthrin 91640-I

Glenda,

Could you also send me an electronic version of the proposed label?

Thanks,

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1

Email: Ciarlo.Timothy@epa.gov

Phone: 703-347-8082

From: Davis, Kable

Sent: Wednesday, July 12, 2017 3:24 PM
To: Glenda Haage <glenda@consultghb.com>

Cc: Ciarlo, Timothy < Ciarlo. Timothy@epa.gov>; Fertich, Elizabeth < fertich.elizabeth@epa.gov>

Subject: FW: Blfenthrin 91640-I

Great - thanks, Glenda.

Hope all is well.

Во

Kable Bo Davis
Acting Branch Chief
Invertebrate & Vertebrate Branch 1
(703) 306-0415
davis.kable@epa.gov

From: Glenda Haage [mailto:glenda@consultghb.com]

Sent: Wednesday, July 12, 2017 3:20 PM Resubmission #3

To: Davis, Kable < Davis Kable @epa gov

Subject: RE: Blfenthrin 91640-I

Hi Bo,

Please find both forms attached. Let me know if you need anything else.

Best regards,

Glenda

Note new email address: glenda@consultghb.com Please update your records.

Glenda Haage GHB Consulting 1660 3rd ave SW LeMars, Iowa 51031 Phone: 712-540-6290

From: Davis, Kable [mailto:Davis.Kable@epa.gov]

Sent: Monday, July 10, 2017 3:15 PM

To: Glenda Haage <glenda@consultghb.com>

Subject: RE: Blfenthrin 91640-I

Sure – that works for me, Glenda. The certification with respect to citation of data form will need to be updated, if you change the date of the data matrix.

From: Glenda Haage [mailto:glenda@consultghb.com]

Sent: Monday, July 10, 2017 4:10 PM
To: Davis, Kable < Davis. Kable@epa.gov>

Subject: RE: Blfenthrin 91640-I

Hi Bo,

Working on the OTP letters now, as soon as my assistant gets them addressed, they will go out in the mail certified. At that time I will send you the new data matrix, but it may be tomorrow, will that be okay? I think my certification with respect to citation of data is okay isn't it?

Thank you.

Note new email address: glenda@consultghb.com Please update your records.

Glenda Haage GHB Consulting 1660 3rd ave SW LeMars, Iowa 51031 Phone: 712-540-6290

From: Davis, Kable [mailto:Davis.Kable@epa.gov]

Sent: Thursday, June 29, 2017 11:29 AM

To: Glenda Haage <glenda@consultghb.com>

Subject: RE: Blfenthrin 91640-I

Great - thanks, Glenda. Have a nice vacation!

From: Glenda Haage [mailto:glenda@consultghb.com]

Sent: Thursday, June 29, 2017 11:16 AM To: Davis, Kable < Davis. Kable@epa.gov>

Subject: RE: Blfenthrin 91640-I

Hi Bo,

After discussing the subject with the client, they have elected to complete a cite-all. I will be submitting the new data matrix stating that the week of July 10 as I will be on vacation next week.

Have a nice holiday. Glenda

Note new email address: glenda@consultghb.com Please update your records.

Glenda Haage GHB Consulting 1660 3rd ave SW LeMars, Iowa 51031 Phone: 712-540-6290

Ciarlo, Timothy

From:

Glenda Haage <glenda@consultghb.com>

Sent:

Wednesday, June 28, 2017 9:52 PM

To:

Ciarlo, Timothy

Cc:

Davis, Kable; Fertich, Elizabeth

Subject:

RE: BIfenthrin 91640-I

Tim,

I was thinking that one of the ombudsman told me there was a generic data matrix template, but maybe I did not understand her correctly.

Thanks, Glenda

Note new email address: glenda@consultghb.com Please update your records.

Glenda Haage GHB Consulting 1660 3rd ave SW LeMars, Iowa 51031 Phone: 712-540-6290

From: Ciarlo, Timothy [mailto:Ciarlo.Timothy@epa.gov]

Sent: Wednesday, June 28, 2017 3:19 PM
To: Glenda Haage <glenda@consultghb.com>

Cc: Davis, Kable <Davis.Kable@epa.gov>; Fertich, Elizabeth <fertich.elizabeth@epa.gov>

Subject: RE: Blfenthrin 91640-I

Hi Glenda,

Unfortunately we do not have the resources to do this for you. If you still wish to selectively cite data, you will need to determine the use patterns on the proposed 91640-I label and associated data requirements per 40 CFR Part 158. The link below contains lists of data requirements according to different use patterns.

https://www.ecfr.gov/cgi-bin/text-idx?SID=738c16c85042ce20aec41a65fa12977e&node=40:24.0.1.1.9&rgn=div5

Once you've done this and included everything on the data matrix, we would then review it to ensure data needs have been addressed.

Alternatively, you could elect to use a cite-all for generic data. I should point out that we are approaching the predecisional due date of 7/17/17 and may need to discuss establishment of a new PRIA date. A cite-all would tremendously expedite things.

Kind Regards,

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1
Email: Ciarlo.Timothy@epa.gov

Phone: 703-347-8082

From: Glenda Haage [mailto:glenda@consultghb.com]

Sent: Wednesday, June 28, 2017 3:26 PM
To: Ciarlo, Timothy < Ciarlo. Timothy@epa.gov>

Subject: RE: Blfenthrin 91640-I

Tim,

Do you have a list of bifenthrin studies I have to fulfill? Then I can just plug in my MRID numbers and make sure I have everything fulfilled.

Thank you.

Note new email address: glenda@consultghb.com Please update your records.

Glenda Haage GHB Consulting 1660 3rd ave SW LeMars, Iowa 51031 Phone: 712-540-6290

From: Ciarlo, Timothy [mailto:Ciarlo.Timothy@epa.gov]

Sent: Wednesday, June 28, 2017 1:40 PM
To: Glenda Haage <glenda@consultghb.com>

Cc: Fertich, Elizabeth <fertich.elizabeth@epa.gov>; Davis, Kable <Davis.Kable@epa.gov>

Subject: RE: Blfenthrin 91640-I

Thanks, Glenda. I will get these studies off to our toxicology team for review. Please remember that there are still outstanding issues regarding generic, product chemistry, and efficacy data. I'm attaching an email which covers these questions in greater detail. In the end, you should end up with a data matrix that is 10 or 15 pages or so in length.

Please let me know if anything is unclear. I'll keep you informed on the tox review.

FYI, Beth Fertich (cc'd) began a 4-month detail as PM 3 this week. Bo Davis is serving a detail as IVB1 Branch Chief.

Kind Regards,

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1

Email: Ciarlo.Timothy@epa.gov

Phone: 703-347-8082

From: Glenda Haage [mailto:glenda@consultghb.com]

Sent: Wednesday, June 28, 2017 2:29 PM

Resubmission # 2

To: Ciarlo, Timothy < Ciarlo. Timothy@epa.gov>

Subject: RE: Blfenthrin 91640-I

Hi Tim,

I think I found it....YAY!

Please see attached. Let me know if you have questions.

Glenda

Note new email address: glenda@consultghb.com Please update your records.

Glenda Haage GHB Consulting 1660 3rd ave SW LeMars, Iowa 51031 Phone: 712-540-6290

From: Ciarlo, Timothy [mailto:Ciarlo.Timothy@epa.gov]

Sent: Tuesday, June 27, 2017 9:38 AM

To: Glenda Haage <glenda@consultghb.com>

Cc: Davis, Kable < Davis.Kable@epa.gov>; Fertich, Elizabeth < fertich.elizabeth@epa.gov>

Subject: RE: Blfenthrin 91640-I

Thanks, Glenda,

I will get these acute tox studies into review. However, where is your waiver request for skin sensitization? Without a rationale for why this data requirement should be waived, it is not likely that it will be granted.

Also, there are other issues which we need to address. I'm attaching an email from 5/4/17 rather than rehash everything. I am also noticing for the first time here that the Product Name on page 2 of the data matrix is incorrect.

Please let me know about the waiver request and the other data matrix questions. It will save us some time down the road if we can correct these things now.

Thanks,

Tim Ciarlo
Entomologist
Environmental Protection Agency
OCSPP/OPP/RD/IVB1

Email: Ciarlo.Timothy@epa.gov

Phone: 703-347-8082

From: Glenda Haage [mailto:glenda@consultghb.com]

Sent: Monday, June 26, 2017 4:51 PM Resubmission # 1

To: Ciarlo, Timothy < Ciarlo. Timothy @epa.gov >

Subject: Blfenthrin 91640-I

Hi Tim,

Attached please find my data matrix in response to your attached letter. Please let me know if the acute tox studies work per our discussion.

Kind regards,

Note new email address: glenda@consultghb.com Please update your records.

Glenda Haage GHB Consulting 1660 3rd ave SW LeMars, Iowa 51031

Phone: 712-540-6290

Ciarlo, Timothy

From:

Piansay, Maria

Sent:

Tuesday, July 18, 2017 10:26 AM

To:

Ciarlo, Timothy

Subject:

RE: Bifenthrin DCIs

Hi Tim – I now confirm -962. Your GDCI and EDSP lists are up-to-date.

From: Ciarlo, Timothy

Sent: Tuesday, July 18, 2017 9:44 AM

To: Piansay, Maria < Piansay. Maria@epa.gov>

Subject: RE: Bifenthrin DCIs

Hi Maria,

Any word on EDSP 128825-962?

Thanks much!

Tim

From: Ciarlo, Timothy

Sent: Monday, July 17, 2017 11:47 AM

To: Piansay, Maria < Piansay. Maria@epa.gov>

Subject: RE: Bifenthrin DCIs

Thanks, Maria! I'll wait for you to find out about -962.

Tim

From: Piansay, Maria

Sent: Monday, July 17, 2017 11:46 AM

To: Ciarlo, Timothy < Ciarlo. Timothy @epa.gov>

Subject: RE: Bifenthrin DCIs

Hi Tim – sorry for the delayed response. I confirm all orders under GDCI are correct. For EDSP, there's one I can't confirm, 962. I could not find any info about this in the files we have (just inherited this chemical). I'll keep digging and let you know. Sorry about that.

Maria

From: Ciarlo, Timothy

Sent: Friday, July 14, 2017 10:10 AM

To: Piansay, Maria < Piansay.Maria@epa.gov > Cc: Biscoe, Melanie < Biscoe.Melanie@epa.gov >

Subject: Bifenthrin DCIs

Hi Maria,

I hope all is well. Could you confirm that the list of DCIs/EDSPs below captures any outstanding data requirements for bifenthrin? We're close to registering a new bifenthrin product down here.

GDCI	128825-902 128825-1114 128825-1158 128825-1159
EDSP	128825-66 128825-67 128825-68 128825-70 128825-71 128825-73 128825-962

Please let me know if you have any questions. Thanks!

Tim Ciarlo Entomologist Environmental Protection Agency OCSPP/OPP/RD/IVB1

Email: Ciarlo.Timothy@epa.gov

Phone: 703-347-8082

